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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Lasse Wesseltoft Mogensen

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EXAMINER

MOULTON, ELIZABETH ROSE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/687,568	<b>Applicant(s)</b> MOGENSEN ET AL.	
	<b>Examiner</b> ELIZABETH R. MOULTON	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1/22/09.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 40-43 and 50-72 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-43, 50-54, 67 and 68 is/are allowed.
- 6) ☒ Claim(s) 55-64 and 69-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Allowable Subject Matter***

1. Claims 40-43, 50-54, 65, 67, and 68 are allowed.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 55, 57, 60, 66, 70-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Miskinyar (US 4,894,054).

Miskinyar teaches an injector device with an infusion set having a housing (74) and a hollow cannula (22), a molded device housing (10), a cover (38 and 72), a plunger (18), a drive (70), a lock (56), and the device housing being manually deformable (button 33) to release the plunger. See Figs 1 and 2. As to claim 60, see cover 62 with hollow 60.

4. Claims 55-57, 60-64, 66, and 69-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Safabash et al (US 6,293,925).

Safabash teaches an injector device with an infusion set having a housing (400) and a cannula (402) with tubing (412); a device housing (500/502), a cover (414 and 416), a

plunger (504), a spring drive (507), lock (552), and manually deformable housing (508) to release the plunger. See Figs 35-40g.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar as applied to claims above, and further in view of Teeple, Jr (US 5,807,316).

Miskinyar does not teach indicia relating to the shelf life of the device on the cover. As to claim 59, see Figs 40a-40d. Teeple teaches that it is known in the art to encode the shelf life of a device in a bar code on the device (Col 18 line 25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the indicia of Teeple to avoid providing an expired device to the patient. The placement of the indicia on the cover is a matter of obvious design choice since placement of the indicia anywhere on the device would have the same effect of notifying the user of expired materials.

***Response to Arguments***

7. Applicant's arguments (see brief pages 15-30) have been considered but are not persuasive.

Miskinyar:

Infusion set: the phrase "infusion set" is not given a special definition in the specification. One ordinary skill in the art would consider a needle an infusion set. Furthermore, there is nothing in the claims that the infusion set is removable, either before or after placement of the needle in the patient. The term "removable" is a capability term and the needle is capable of being removed by cutting ,etc. In a device claim, the device must only be CAPABLE not INTENDED or DISCLOSED as performing the claimed function. There is no "plain meaning" of the term "infusion set" which limits an infusion set to a device removable from an "injector device" (which is also NOT given a special definition). An infusion set may be a pump, an IV bag, essentially anything with a fluid conduit for subcutaneous fluid delivery.

Cover: Miskinyar teaches two covers: 72 and 38. Cover 72 closes off a part of the infusion set as shown in Fig 2. The cover also "receives" a part of the infusion device when the needle pierces the tape, Fig 3. The hole through which the needle extends is obviously hollow. The examiner notes that the "front end portion" of the housing can be EITHER end of the housing.

Manually deformable housing: the button 33 is a part of the housing, generally housing 10. Applicant has absolutely no basis for asserting that the button, which actually forms a top of the housing, should no be considered a housing. Applicant asserts this does not fit the plain meaning of housing, but does NOT describe what such a plain meaning would be. The button moves up

and down, which makes it manually deformable from a first (up) to a second (down) position. The button may be pushed at the sides to deploy the plunger.

Safabash:

Housing: the button 508 is a part of the housing, generally housing 502. Applicant has absolutely no basis for asserting that the button, which actually forms a top of the housing, should not be considered a housing. Applicant asserts this does not fit the plain meaning of housing, but does NOT describe what such a plain meaning would be. The button moves up and down, which makes it manually deformable from a first (up) to a second (down) position. The button may be pushed at the sides to deploy the plunger. The prior art does not need to refer to its device using the same terminology as the applicant. References to Funderbunk are completely irrelevant as Safabash discloses an entirely different embodiment of the infusion placement device.

Cover: The term "removably connected" does not require a direct bond between the device housing and the cover. The cover is connected to the housing via the insertion set, as is clearly shown in Fig 40b. Safabash teaches a needle cover (414) and adhesive backing (416) COVERING adhesive 406

Miskinyar and Teeple:

Miskinyar and Teeple are both related to subcutaneous injections which places them in related fields of endeavor. The desire to improve the safety of medical devices is a well recognized motivation for improvement. In this case, Teeple teaches labeling a medical device with expiration data. It would be a clear

case of improving similar devices in the same way to add expiration data to the device of Miskinyar.

### ***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ELIZABETH R. MOULTON** whose telephone number is (571)272-9970. The examiner can normally be reached on 7:00-3:30 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELIZABETH R MOULTON/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767